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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/089,583	07/11/2002	Joyce S. Plested	11560-003US1	2536

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EITAN, PEARL, LATZER & COHEN ZEDEK LLP
10 ROCKEFELLER PLAZA, SUITE 1001
NEW YORK, NY 10020

EXAMINER

DEVI, SARVAMANGALA J N

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 05/16/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/089,583

Applicant(s)

PLESTED ET AL.

Examiner

S. Devi, Ph.D.

Art Unit

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 February 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 48-61 ~~is/are~~ are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 48-61 ~~is/are~~ are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

Request for Continued Examination

- 1) A request for continued examination under 37 C.F.R. 1.114, including the fee set forth in 37 C.F.R. 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 C.F.R. 1.114, and the fee set forth in 37 C.F.R. 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 C.F.R. 1.114. Applicants' submission filed on 02/25/05 has been entered.

Applicants' Amendment

- 2) Acknowledgment is made of Applicants' amendment filed 02/22/05 in response to the final Office Action mailed 08/25/04. With this, Applicants have amended the specification.

Status of Claims

- 3) Claims 1-18, 20-28 and 42-47 have been canceled via the amendment filed 02/25/05.
New claims 48-61 have been added via the amendment filed 02/25/05.
Claims 48-61 are pending and are under examination.

Prior Citation of Title 35 Sections

- 4) The text of those sections of Title 35 U.S. Code not included in this action can be found in a prior Office Action.

Prior Citation of References

- 5) The references cited or used as prior art in support of one or more rejections in the instant Office Action and not included on an attached form PTO-892 or form PTO-1449 have been previously cited and made of record.

Objection(s) Withdrawn

- 6) The objection to the specification made in paragraph 5(iv) of the Office Action mailed 01/08/04 and maintained in paragraph 14 of the Office Action mailed 08/25/04 is withdrawn in light of Applicants' arguments.

Rejection(s) Moot

- 7) The rejection of claims 24 and 25 made in paragraph 7 of the Office Action mailed 01/08/04 and maintained in paragraph 48 of the Office Action mailed 08/25/04 under 35 U.S.C. § 112, first

paragraph, with regard to the deposit issue, is moot in light of Applicants' cancellation of the claims.

8) The rejection of claims 1-18 and 20-23 made in paragraph 13 of the Office Action mailed 01/08/04 and maintained in paragraph 49 of the Office Action mailed 08/25/04 under 35 U.S.C § 102(b) as being anticipated by Plested *et al.* (*Infect. Immun.* 67: 5417-5426, October 1999 - Applicants' IDS), is moot in light of Applicants' cancellation of the claims.

9) The rejection of claims 1-12, 14-18, 20-22 and 26 made in paragraph 14 of the Office Action mailed 01/08/04 and maintained in paragraph 50 of the Office Action mailed 08/25/04 under 35 U.S.C § 102(b) as being anticipated by Verheul *et al.* (*Infect. Immun.* 59: 843-851, 1991, already of record) as evidenced by Plested *et al.* (*Infect. Immun.* 67: 5417-5426, October 1999 - Applicants' IDS), is moot in light of Applicants' cancellation of the claims.

10) The rejection of claims 9 and 10 made in paragraph 51 of the Office Action mailed 08/25/04 under 35 U.S.C § 112, first paragraph, as being as containing new subject matter, is moot in light of Applicants' cancellation of the claims.

11) The rejection of claim 20 made in paragraph 52 of the Office Action mailed 08/25/04 under 35 U.S.C § 112, first paragraph, as containing new subject matter, is moot in light of Applicants' cancellation of the claims.

12) The rejection of claims 1-18, 20-23 and 26-28 made in paragraph 53 of the Office Action mailed 08/25/04 under 35 U.S.C. § 112, first paragraph, as containing subject matter, is moot in light of Applicants' cancellation of the claims.

13) The rejection of claims 1-18, 20-23 and 26-28 made in paragraph 54 of the Office Action mailed 08/25/04 under 35 U.S.C § 112, second paragraph, as being indefinite, is moot in light of Applicants' cancellation of the claims.

14) The rejection of claims 1-18, 20-23, 26 and 27 made in paragraph 55 of the Office Action mailed 08/25/04 under 35 U.S.C § 102(b) as being anticipated by Hoogerhout *et al.* (NL 9,101,359 - original and English translated document) as evidenced by Goldschneider *et al.* (*J. Exp. Med.* 129: 1307-1326, 1969), is moot in light of Applicants' cancellation of the claims.

Rejection(s) under 35 U.S.C. § 112, First Paragraph (New Matter)

15) Claims 48-61 are rejected under 35 U.S.C § 112, first paragraph, as being as containing

subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

The limitations in the instant new claims: 'a plurality of *Neisseria* immunotypes'; 'three or more *Neisseria* immunotypes'; 'four or more *Neisseria* immunotypes'; and 'five or more *Neisseria* immunotypes', constitute new matter, because there is no descriptive support for these limitations in the instant specification, as originally filed. The term '*Neisseria*' represents the whole genus and encompasses several pathogenic and non-pathogenic species other than *Neisseria meningitidis*. Table 2 and lines 17 and 18 of page 31 show that the Mab B5 reacted with immunotypes L1, L3 and L7-12 of *Neisseria meningitidis*. However, this description does not support the lower and the limitless upper range of the new limitations now recited: 'three or more *Neisseria* immunotypes'; 'four or more *Neisseria* immunotypes'; 'five or more *Neisseria* immunotypes'. The reactivity with the recited immunotypes of any species of '*Neisseria*' other than *Neisseria meningitidis* is not supported in the specification, as originally filed. Therefore, the limitations in the claims are considered to be new matter. *In re Rasmussen*, 650 F2d 1212 (CCPA, 1981). New matter includes not only the addition of wholly unsupported subject matter but also, adding specific percentages or compounds after a broader original disclosure, or even omission of a step from a method. See M.P.E.P 608.04 to 608.04(c).

Applicants are respectfully requested to remove the new matter from the claim(s), or to point to specific pages and line numbers in the originally filed specification where support for such recitations can be found.

Rejection(s) under 35 U.S.C. § 112, Second Paragraph

16) Claims 50-53 and 60 are rejected under 35 U.S.C § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention.

(a) Claim 53 lacks proper antecedence in the limitation: 'five or more *Neisseria* immunotypes'. Claim 53 depends from claim 52, which includes the same limitation. For proper antecedence, and to be consistent with the language used in claim 60, it is suggested that Applicants replace the limitation with --said five or more *Neisseria* immunotypes--.

(b) Claims 50-53 and 60 are incorrect and inconsistent with the rest of the claims with regard to the recitation 'whereby' as opposed to --wherein--.

Rejection(s) under 35 U.S.C. § 102

17) Claims 48-61 are rejected under 35 U.S.C § 102(b) as being anticipated by Arumugham *et al.* (EP 0941738, already of record) as evidenced by Plested *et al.* (*J. Immunol. Methods* 237: 73-84, 2000 – Applicants' IDS) (Plested *et al.*, 2000).

Arumugham *et al.* disclosed a method of immunizing mice with an immunogenic conjugate composition comprising a conserved inner core portion of a meningococcal or gonococcal lipopolysaccharide (LPS) comprising a phosphoethanolamine group linked to position 3 of HepII of the inner core of the LPS. The LPS portion present in the vaccine contains only the conserved core LPS structure of *Neisseria meningitidis* having a structure identified by GlcNAc-Hep₂phosphoethanolamine-KDO₂. See section 'Immunogenicity Determination'; Table 2; section [0046]; and Figures 2 and 3. The LPS in the conjugate is a truncated LPS from a *galE* mutant of *Neisseria meningitidis* wherein no galactose is added to the core portion (see sections 0023 and 0024). The prior art method elicited antibodies which recognized or were reactive with the purified LPS or the whole cells of majority of the strains of *Neisseria meningitidis*, including R6, AI, H44/76 and 2996 strains, and a plurality of *Neisseria meningitidis* immunotypes exceeding five immunotypes in number: L1, L3, L5, L7, L8, L10 and L11. See sections [0053] to [0055] and [0058]; and Table 2. That the LPS from the prior art *galE* mutant of *Neisseria meningitidis* lacks outer core is inherent from the teachings of Arumugham *et al.* in light of what is well known in the art. For instance, Plested *et al.* (2000) taught that mutants of *galE* produce a truncated form of LPS lacking galactose and other sugars distal to this, i.e., outer core (see first full sentence in right column on page 74).

Claims 48-61 are anticipated by Arumugham *et al.* Plested *et al.* (2002) is **not** used as a secondary reference in combination with Arumugham *et al.*, but rather is used to show that every element of the claimed subject matter is disclosed by Arumugham *et al.* with the unrecited limitation(s) being inherent as evidenced by the state of the art. See *In re Samour* 197 USPQ 1 (CCPA 1978).

Remarks

18) Claims 48-61 stand rejected.

19) Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted via the PTO Fax Center which receives transmissions 24 hours a day and 7 days a week. The transmission of such papers by facsimile must conform with the notice published in the Official Gazette, 1096 OG 30, November 15, 1989. The central Fax number for submission of amendments, responses and papers is (703) 872-9306.

20) Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAG or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.Mov>. Should you have questions on access to the Private PAA system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

21) Any inquiry concerning this communication or earlier communications from the Examiner should be directed to S. Devi, Ph.D., whose telephone number is (571) 272-0854. The Examiner can normally be reached on Monday to Friday from 7.15 a.m. to 4.15 p.m. except one day each bi-week, which would be disclosed on the Examiner's voice mail system. A message may be left on the Examiner's voice mail system.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Lynette Smith, can be reached on (571) 272-0864.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

May, 2005


S. DEVI, PH.D.
PRIMARY EXAMINER